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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/109,082 07/02/98 MELKI

J 2121-140P

HM12/0825
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EXAMINER

HAYES, R.

ART UNIT

PAPER NUMBER

1645

4

DATE MAILED:

08/25/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/109,082

Applicant(s)

Melki et al

Examiner

Robert C. Hayes

Group Art Unit

1645

☒ Responsive to communication(s) filed on Jul 2, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-52 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-52 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. This requirement can be obviated by a letter transferring the CRF of parent application, 08/459046, to the instant application, and a statement that these sequences are identical to that of the instant application and contain no new matter. It should also be noted that 37 CFR 1.821 (a)(2)(c-d) states that each sequence disclosed must appear separately in the "Sequence listing" *and* in the text of the description and claims (i.e., where first mentioned in the specification). See MPEP 2431.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1-2 & 18-20, drawn to an isolated survival motor neuron (SMN) protein, classified in class 530, subclass 350.
 - II. Claims 3-13, 17, 24-29 & 37, drawn to nucleic acids encoding SMN proteins, vectors, full length antisense probes, and host cells, classified in class 435, subclass 69.1.
 - III. Claims 14-16, drawn to oligonucleotides, classified in class 536, subclass 24.31.

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- IV. Claims 21-23, 30-34, 36 & 40-52, drawn to kits and methods of detecting motor neuron diseases comprising use of nucleic acids, classified in Class 435, subclass 6.
- V. Claim 35, drawn to antibodies of the SMN protein, classified in Class 530, subclass 387.1.
- VI. Claims 38-39, drawn to transgenic mice, classified in Class 800, subclass 2.

3. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in MPEP § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper, because these products appear to constitute patentably distinct inventions for the following reasons:

Groups I-III & V-VI are directed to products that are physically and functionally distinct; involving proteins, nucleic acids, oligonucleotide probes, antibodies, and transgenic animals. All of these products can be prepared by different processes, such as through chemical synthesis or isolation from natural sources using various isolation/purification procedures, or through unique genetic manipulation and implantation protocols using embryos (i.e., as it relates to Group VI). For example, the proteins of Group I and antibodies of Group V are fundamentally different molecules than the nucleic acid molecules of Groups II or III, which in turn can be used to clone the protein, make vaccines, or used as therapeutic agents in gene therapy. Although the antibodies of Group V can be used in isolating the protein of Group I, the antibodies of Group V

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can be generated by immunizing animals with a small synthetic portion of the full length protein, and can be used diagnostically in other ways, such as in affinity chromatography or in immunoassays, or as therapeutic agents themselves. The protein of Group I can be utilized in making the antibodies of Group V, but not vice versa. Although the oligonucleotide primers of Group III and the nucleic acid molecules of Group II are polynucleotides, each of these groups have different structures and functions. Structurally, the short oligonucleotides of Group II are generally smaller molecules than the nucleic acid molecules of Group I, and do not usually constitute a functional gene. Even though the oligonucleotide primers of Group II can hybridize to the molecules of Group I, these molecules are usually radioactively labeled or biotinylated, or require inclusion of polymerases to use, which are not required in Group II. Finally, although the transgenic animals of Group VI can be used to study the effects of expression and activity of the polynucleotides of Group II and the proteins of Group I, they themselves can not make a transgenic animal, alone. It is pointed out that there is a proper distinction between these groups, since each product is not required in order for the other to exist. Thereby, these groups are distinct and separable for the reasons stated.

Groups II-III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the polynucleotides of Groups II-III can be used in materially

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different methods, such as to clone the SMN protein or used as therapeutic agents in gene therapy. In contrast, the method of detecting SMN genes with nucleic acids of Group IV requires specific tissue or cell preparations, nucleic acid labeling and amplification reactions, as well as patients with specific disease states, which are not required in Groups II-III.

It is further noted that the method of Group IV does not require the products of Groups I, V or VI, and vice versa.

Because these inventions are distinct for the reasons given above, they have acquired a separate status in the art as shown by their different classification, and the non-coextensiveness of the search and examination for each group would constitute an undue burden on the examiner to search and consider all the separable groups with their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.
August 23, 1999


PATRICIA A. DUFFY
PRIMARY EXAMINER

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☐ 7. Other: _____

Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

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